IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| PFIZER INC., C.P. PHARMACEUTICALS INTERNATIONAL C.V., PF PRISM C.V., PBG PUERTO RICO LLC, and PF PRISM IMB B.V., | ) | |
| Plaintiffs, | ) | C.A. No. _____ |
| v. | ) | |
| ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LTD., | ) | |
| Defendants. | ) | |

**COMPLAINT**

Pfizer Inc., C.P. Pharmaceuticals International C.V., PF PRISM C.V., PBG Puerto Rico LLC, and PF PRISM IMB B.V. (collectively "Plaintiffs" or "Pfizer"), for their Complaint against Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. (collectively "Defendants" or "Zydus"), allege as follows:

**NATURE OF THE ACTION**

1. This is an action by Pfizer against Zydus for infringement of United States Patent No. RE41,783 ("the RE'783 patent"), United States Patent No. 6,965,027 ("the '027 patent"), and United States Patent No. 7,301,023 ("the '023 patent").

2. This action arises out of Zydus's filing of ANDA No. 214264 seeking approval by the FDA to sell generic copies of Xeljanz XR® (tofacitinib extended-release tablets, 11 mg) prior to the expiration of the RE'783, '027, and '023 patents.

## THE PARTIES

3. Plaintiff Pfizer is a corporation organized and existing under the laws of the state of Delaware and having a place of business at 235 East 42nd Street, New York, New York 10017.

4. Plaintiff C.P. Pharmaceuticals International C.V. is a limited partnership (*commanditaire vennootschap*) organized under the laws of the Netherlands, having a place of business at 235 East 42nd Street, New York, New York 10017, and Pfizer Inc. is the ultimate parent company of C.P. Pharmaceuticals International C.V.

5. Plaintiff PF PRISM C.V. is a limited partnership (*commanditaire vennootschap*) organized under the laws of the Netherlands, having its registered seat in Rotterdam, the Netherlands, and registered at the Trade Register held by the Chamber of Commerce in Rotterdam, the Netherlands, under number 51840456, and Pfizer Inc. is the ultimate parent company of PF PRISM C.V.

6. Plaintiff PBG Puerto Rico LLC is a limited liability company organized and existing under the laws of Puerto Rico and having its principal place of business at Professional Offices Park V, 996 San Roberto Street, 4th Floor, San Juan, Puerto Rico 00926, and Pfizer Inc. is the ultimate parent company of PBG Puerto Rico LLC.

7. Plaintiff PRISM IMB B.V. is a private limited liability company (*besloten vennootschap*) under Dutch law, having its registered seat in Rotterdam, the Netherlands, having its business address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJssel, the Netherlands, and registered with the Dutch Trade Register under number 60558814, and Pfizer Inc. is the ultimate parent company of PF Prism IMB B.V.

8. On information and belief, defendant Cadila Healthcare Ltd. is a company organized and existing under the laws of India, having its principal place of business at Zydus Tower, Satellite Cross Roads, Sarkhej-Gandhinagar Highway, Ahmedabad, India, 380 015.

9. On information and belief, defendant Zydus Pharmaceuticals (USA) Inc. is a company organized and existing under the laws of New Jersey, having its principal place of business at 73 Route 31 N., Pennington, NJ 08534. On information and belief, Cadila Healthcare Ltd. is the ultimate parent company of Zydus Pharmaceuticals (USA) Inc. On information and belief, Zydus Pharmaceuticals (USA) Inc. is the U.S. agent for Cadila Healthcare Ltd.

## JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States, Title 35, United States Code. The Court has subject matter jurisdiction over this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. This Court has personal jurisdiction over Defendants, and venue is proper in this action.

12. Defendants did not contest personal jurisdiction and venue in this court in a previously filed, pending litigation between the same parties regarding the same patents at issue in this case. *See* D.I. 83 in *Pfizer Inc. et al. v. Zydus Pharmaceuticals (USA) Inc. et al.*, C.A. No. 17-158-GJP (D. Del.).

13. In the alternative, this Court has personal jurisdiction over Zydus by virtue of the fact that, *inter alia*, it has committed a tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiffs, including in Delaware. In particular, this suit arises out of Zydus Pharmaceuticals (USA) Inc.'s filing of ANDA No. 214264 seeking FDA approval to sell generic copies of Xeljanz XR prior to the expiration of the RE'783, '027, and '023 patents, throughout the United States, including in Delaware.

14. In the alternative, this Court has jurisdiction over Cadila Healthcare Ltd. under Federal Rule of Civil Procedure 4(k)(2). Cadila Healthcare Ltd. has contacts with the United States by, *inter alia*, having caused the filing of Zydus Pharmaceuticals (USA) Inc.'s ANDA with the FDA.

## BACKGROUND

### Xeljanz XR

15. Pfizer Inc. holds approved NDA No. 208246 for EQ 11 mg base tofacitinib citrate extended-release tablets, which it sells under the registered name Xeljanz XR. The active ingredient in Xeljanz XR is tofacitinib citrate. Xeljanz XR contains tofacitinib citrate in an amount equivalent to 11 mg of tofacitinib base in an extended release tablet formulated for once-daily administration.

16. Tofacitinib citrate is an inhibitor of Janus kinases ("JAKs") and is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate, for the treatment of adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs (DMARDs), and for the treatment of adult patients with moderately to severely active ulcerative colitis who have an inadequate response or who are intolerant to TNF blockers.

17. The FDA-approved Prescribing Information for Xeljanz XR states that tofacitinib citrate has the following chemical name: (3R,4R)-4-methyl-3-(methyl-7H-pyrrolo [2,3-d] pyrimidin-4-ylamino)-ß-oxo-1-piperidinepropanenitrile, 2-hydroxy-1,2,3-propanetricarboxylate (1:1).

**Orange Book Listing for Xeljanz XR**

18. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA has promulgated pursuant thereto, the RE'783, '027, and '023 patents are listed in the FDA publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") for the Xeljanz XR NDA.

19. The Orange Book lists the expiration date for the RE'783 patent as December 8, 2025, the '027 patent as March 25, 2023, and the '023 patent as May 23, 2022. The '023 patent is subject to a terminal disclaimer relative to the RE'783 patent and therefore expires on December 8, 2020.

20. The Orange Book also lists five additional patents for Xeljanz XR that are not at issue: U.S. Patent Nos. 6,956,041 (expiring December 8, 2020); 7,091,208 (expiring December 8, 2020); 7,265,221 (expiring December 8, 2020); 7,842,699 (expiring December 8, 2020); and 9,937,181 (expiring March 14, 2034).

**The RE'783 Patent**

21. On September 28, 2010, the USPTO issued the RE'783 patent, titled "Pyrrolo[2,3-d]pyrimidine Compounds." The RE'783 patent is a reissue of U.S. Patent No. 6,627,754, which issued on September 30, 2003. The RE'783 patent is duly and legally assigned to Pfizer Inc. A copy of the RE'783 patent is attached hereto as Exhibit A.

22. On December 14, 2016, the United States Patent and Trademark Office ("USPTO") issued a Notice of Final Determination extending the expiration date of the RE'783 patent to December 8, 2025.

23. C.P. Pharmaceuticals International C.V. is the exclusive licensee of the RE'783 patent.

24. C.P. Pharmaceuticals International C.V. conveyed rights under the RE'783 patent to Pfizer Pharmaceuticals LLC, PF PRISM C.V., and Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V.

25. Pfizer Pharmaceuticals LLC has conveyed its rights to the RE'783 patent to PBG Puerto Rico LLC.

26. Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. has conveyed its rights to the RE'783 patent to PF PRISM IMB B.V.

**The '027 Patent**

27. On November 15, 2005, the USPTO issued the '027 patent, titled "Crystalline 3-{4-methyl-3-[methyl-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-amino]-piperidin-1-yl}-3-oxo-propionitrile citrate." The '027 patent is duly and legally assigned to Pfizer Inc. A copy of the '027 patent is attached hereto as Exhibit B.

28. C.P. Pharmaceuticals International C.V. is the exclusive licensee of the '027 patent.

29. C.P. Pharmaceuticals International C.V. conveyed rights under the '027 patent to Pfizer Pharmaceuticals LLC, PF PRISM C.V., and Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V.

30. Pfizer Pharmaceuticals LLC has conveyed its rights to the '027 patent to PBG Puerto Rico LLC.

31. Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. has conveyed its rights to the '027 patent to PF PRISM IMB B.V.

**The ’023 Patent**

32. On November 27, 2007, the USPTO issued the ’023 patent, titled “Chiral Salt Resolution.” The ’023 patent is duly and legally assigned to Pfizer Inc. A copy of the ’023 patent is attached hereto as Exhibit C.

33. C.P. Pharmaceuticals International C.V. is the exclusive licensee of the ’023 patent.

34. C.P. Pharmaceuticals International C.V. conveyed rights under the ’023 patent to Pfizer Pharmaceuticals LLC, PF PRISM C.V., and Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V.

35. Pfizer Pharmaceuticals LLC has conveyed its rights to the ’023 patent to PBG Puerto Rico LLC.

36. Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. has conveyed its rights to the ’023 patent to PF PRISM IMB B.V.

**Zydus’s ANDA**

37. By letter dated January 14, 2020 (the “Zydus Notice Letter”) and received by Pfizer on January 15, 2020, Zydus notified Pfizer that it had submitted ANDA No. 214264 to the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act (“FDCA”) to market and sell Zydus Generic XR Tablets – generic copies of Xeljanz XR (tofacitinib citrate EQ 11 mg base extended-release tablets) – prior to the expiration of the RE’783, ’027, and ’023 patents.

38. The Zydus Notice Letter asserts that ANDA No. 214264 contains a “Paragraph IV” certification under 21 U.S.C. §§ 355(j)(2)(B)(iv) alleging that “no valid claim of [the RE’783, ’027, and ’023 patents] will be infringed by the manufacture, use, or sale of” Zydus Generic XR Tablets.

39. On information and belief Zydus Generic XR Tablets will contain tofacitinib citrate as the active ingredient.

40. On information and belief Cadila Healthcare Ltd. holds DMF No. 30531 for tofacitinib citrate.

41. The Zydus Notice Letter states that ANDA No. 214264 seeks "to obtain approval to engage in the commercial manufacture, use or sale of" Zydus Generic XR Tablets prior to the expiration of the RE'783, '027, and '023 patents.

42. Attached to the Zydus Notice Letter was Zydus's Detailed Factual and Legal Bases in Support of Its Paragraph IV Certification for Tofacitinib Extended-Release Tablets, 11 mg ("Zydus's Detailed Statement") asserting the purported factual and legal bases for Zydus's contention that the RE'783, '027, and '023 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, and/or sale of Zydus Generic XR Tablets.

43. Zydus's Detailed Statement alleges that all claims of the RE'783, '027, and '023 patents are invalid. Other than with respect to claim 5 of the '027 patent, Zydus's Detailed Statement does not contain a noninfringement argument with respect to the RE'783, '027, and '023 patents, other than that all claims are invalid.

44. On information and belief, Cadila Healthcare Ltd. and Zydus Pharmaceuticals (USA) Inc. collaborated and acted in concert in the decision to prepare and file and in the preparation and filing of ANDA No. 214264.

45. On information and belief, upon approval of ANDA No. 214264, Zydus will distribute Zydus Generic XR Tablets in the United States.

**COUNT I**
**(Infringement of the RE'783 Patent by Zydus Generic XR Tablets)**

46. The allegations of paragraphs 1-45 above are repeated and re-alleged as if set forth fully herein.

47. Pursuant to 35 U.S.C. § 271(e)(2)(A), Zydus Pharmaceuticals (USA) Inc.'s filing of ANDA No. 214264 seeking approval to market Zydus Generic XR Tablets is an act of infringement of one or more claims of the RE'783 patent entitling Pfizer to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 214264 be a date which is not earlier than the expiration date of the RE'783 patent.

48. Zydus had knowledge of the RE'783 patent when it submitted ANDA No. 214264 to the FDA.

49. On information and belief, upon FDA approval, Zydus intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Zydus Generic XR Tablets and will thereby infringe at least claims 3 and 4 of the RE'783 patent.

50. The foregoing actions by Zydus constitute and/or would constitute infringement of at least claims 3 and 4 of the RE'783 patent.

51. Pfizer will be substantially and irreparably harmed if Zydus is not enjoined from infringing the RE'783 patent. Pfizer has no adequate remedy at law.

**COUNT II**
**(Infringement of the '027 Patent by Zydus Generic XR Tablets)**

52. The allegations of paragraphs 1-51 above are repeated and re-alleged as if set forth fully herein.

53. Pursuant to 35 U.S.C. § 271(e)(2)(A), Zydus Pharmaceuticals (USA) Inc.'s filing of ANDA No. 214264 seeking approval to market Zydus Generic XR Tablets is an act of

infringement of at least claim 1 of the '027 patent entitling Pfizer to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 214264 be a date which is not earlier than the expiration date of the '027 patent.

54. Zydus had knowledge of the '027 patent when it submitted ANDA No. 214264 to the FDA.

55. On information and belief, upon FDA approval, Zydus intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Zydus Generic XR Tablets and will thereby infringe at least claim 1 of the '027 patent.

56. The foregoing actions by Zydus constitute and/or would constitute infringement of at least claim 1 of the '027 patent.

57. Pfizer will be substantially and irreparably harmed if Zydus is not enjoined from infringing the '027 patent. Pfizer has no adequate remedy at law.

**COUNT III**
**(Infringement of the '023 Patent by Zydus Generic XR Tablets)**

58. The allegations of paragraphs 1-57 above are repeated and re-alleged as if set forth fully herein.

59. Pursuant to 35 U.S.C. § 271(e)(2)(A), Zydus Pharmaceuticals (USA) Inc.'s filing of ANDA No. 214264 seeking approval to market Zydus Generic XR Tablets is an act of infringement of claim 1 of the '023 patent entitling Pfizer to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 214264 be a date which is not earlier than the expiration date of the '023 patent.

60. Zydus had knowledge of the '023 patent when it submitted ANDA No. 214264 to the FDA.

61. On information and belief, upon FDA approval, Zydus intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Zydus Generic XR Tablets and will thereby infringe claim 1 of the ’023 patent.

62. The foregoing actions by Zydus constitute and/or would constitute infringement of claim 1 of the ’023 patent.

63. Pfizer will be substantially and irreparably harmed if Zydus is not enjoined from infringing the ’023 patent. Pfizer has no adequate remedy at law.

**PRAYER FOR RELIEF**

WHEREFORE, Pfizer requests the following relief:

A. A judgment that Zydus’s submission of ANDA No. 214264 was an act of infringement and that Zydus’s making, using, offering to sell, selling, or importing Zydus Generic XR Tablets prior to the expiration of the RE’783, ’027, and ’023 patents will infringe those patents;

B. A judgment that the effective date of any FDA approval for Zydus to make, use, offer for sale, sell, market, distribute, or import the Zydus Generic XR Tablets be no earlier than the dates on which the RE’783, ’027, and ’023 patents expire, or any later expiration of exclusivity to which Pfizer is or becomes entitled;

C. A permanent injunction enjoining Zydus, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making, using, selling, offering for sale, marketing, distributing, or importing Zydus Generic XR Tablets, and from inducing or contributing to any of the foregoing, prior to the expiration of the RE’783, ’027, and ’023 patents, or any later expiration of exclusivity to which Pfizer is or becomes entitled;

D. A judgment that this case is an exceptional case under 35 U.S.C. § 285, entitling Pfizer to an award of its reasonable attorneys' fees for bringing and prosecuting this action;

E. An award of Pfizer's costs and expenses in this action; and

F. Such further and additional relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Megan E. Dellinger*

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